REDACTED VERSION – PUBLICLY FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LIMITED Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED Defendants.	)	Civil Action No. 04-171-KAJ **CONFIDENTIAL** **FILED UNDER SEAL**

TEVA'S BRIEF IN OPPOSITION TO GLAXO'S MOTION FOR SUMMARY JUDGMENT OF PATENT INFRINGEMENT

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I. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDING

This is a patent infringement action initiated by Glaxo following Teva's submission of an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j) to the Food and Drug Administration ("the FDA") for approval of a generic formulation of Glaxo's Zantac® oral solution, a brand-name drug covered by U.S. Patent No. 5,068,249 ("the '249 patent"). Glaxo has conceded that the '249 patent claims do not literally cover Teva's ranitidine oral solution because the claims require the inclusion of ethanol, while Teva's formulation does not include ethanol.

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Teva's generic formulation is different from the claims of the '249 patent because it includes rather than ethanol, among other differences.

For its part, Teva has admitted that its formulation has all of the elements of the claims of the '249 patent except: 1) "a stabilizing effective amount of;" 2) "ethanol;" 3) "2.5% to 10% weight/volume ethanol;" and 4) "7% to 8% weight/volume ethanol." Glaxo has moved for summary judgment of patent infringement, asserting Teva's generic formulation infringes all claims of the '249 patent under the doctrine of equivalents.

II. SUMMARY OF THE ARGUMENT

Glaxo's motion should be denied because "ethanol" in the claims of the '249 patent can have no range of equivalents beyond "ethanol." Teva's affirmative motion for summary judgment sets forth in detail that five distinct legal and policy limitations on the use of the doctrine of equivalents prevent Glaxo from expanding the claims of the '249 patent beyond the disclosed and claimed "ethanol." (D.I. No. 104). Teva's position is that the doctrine of equivalents is not available to Glaxo in this matter but, for sake of

brevity, those arguments will not be repeated here. Those arguments alone, however, justify the denial of Glaxo's motion.

Assuming this Court deems some range of equivalents to be appropriate, then Glaxo's motion also should be denied because Glaxo has failed to prove that the in Teva's formulation meets the claim term "ethanol" under the doctrine of equivalents. Moreover, Glaxo has failed to prove infringement of claims 1-10 because there is no evidence that , in any amount, meets the claim term "stabilizing effective amount." It is not disputed that the use of buffering salts and other preservatives enhance the stability of ranitidine oral solutions (which are in Teva's formulation), and Glaxo cannot prove that the addition of contributes in any manner to the stability of Teva's formulation. At the very least, genuine issues of material fact preclude judgment as a matter of law on the question of whether Teva's formulation infringes under the doctrine of equivalents, assuming Glaxo is entitled to expand its claims under the doctrine in any respect.

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This Court also should reject Glaxo's request for a negative inference of patent infringement. Glaxo not only has the document in question, but also relies on the document to support its motion. Glaxo's improper discovery motion (never mentioned to Teva until now) is based on nothing but naked inferences that are built upon a blatant mischaracterization of the record. Glaxo hopes to conjure a false impression of discovery misconduct, where none exists. There is no legal or factual basis for the severe evidentiary sanction Glaxo requests, and the Court should deny Glaxo's request.

III. STATEMENT OF THE FACTS

Glaxo's Statement of Facts omits important context and ignores other material facts necessary for this Court's evaluation of the viability of Glaxo's motion.

A. The Experts Do Not Agree That In Teva's Formulation Performs The Same Functions As Ethanol.

Glaxo's expert opinion is contradicted, not confirmed, by the analysis of Teva's expert, Professor Arthur H. Kibbe, Ph.D. Professor Kibbe unequivocally concludes, in his opening report, as follows:

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(Exhibit 15 at A098, Kibbe Report, March 14, 2006, ¶ 86) (original emphasis). Dr. Kibbe also concludes that

(*Id.* at A093, ¶ 66.) Moreover, Dr. Kibbe advises, and Glaxo does not dispute, that the basic chemical structure of is significantly different from ethanol. (*Id.* at A095-A097, ¶¶ 76-83.) Dr. Kibbe concludes

(*Id.* at A097, ¶ 82.)

Dr. Kibbe also will testify[1] in rebuttal to Dr. Anderson's analysis. Dr. Kibbe's rebuttal report explains in detail that Dr. Anderson's analysis is

' (Exhibit 16 at A101, Kibbe Rebuttal Report, April 24, 2006, ¶ 5). Ultimately, Dr. Kibbe concludes that

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(*Id.* at ¶ 3b.)

Dr. Kibbe also specifically challenges Dr. Anderson's conclusion concerning the in which ethanol stabilizes ranitidine in oral solutions in comparison to Teva's formulation. Dr. Kibbe notes that the impurities measured in each of Dr. Anderson's tests degrade at rates that are (*Id.* at A104, ¶ 14.) (emphasis added). Using Dr. Anderson's own tables, Dr. Kibbe concludes:

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(*Id.* at A104-105, ¶ 15.) Dr. Kibbe, after further analyzing the degradants shown in Dr. Anderson's report, concludes that '

(*Id.* at A107, ¶ 24.)

B. Glaxo's Summary Of Its Own Expert Opinion Omits A Critical Failure Of Proof.

Dr. Kibbe's report refutes the conclusions reached by Dr. Anderson. This, by itself, creates fact issues for the Court to decide. Putting Dr. Kibbe's opinions aside,

[1] Neither party contends the other's respective expert evidence is not admissible under Rule 702 of the Federal Rules of Evidence, as no *Daubert* motions have been filed.

however, even Glaxo's own expert report and deposition testimony fail to make out a case of infringement under the doctrine of equivalents. Dr. Anderson presented no evidence to this Court proving that performs all of the functions of ethanol in an oral ranitidine solution.

Dr. Anderson, in his first of several expert reports, declared that ethanol performs

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(Exhibit 1 at A002, Anderson Report, March 16, 2006, ¶ 40). Dr. Anderson confirmed in his deposition that, as taught by the '249 patent,

(Exhibit 17 at A132-A133, Anderson Depo. pp. 71-72). As a confirmation of Dr. Anderson's opinion, Dr. Long, the inventor of the '249 patent, abandoned because it did not perform the antimicrobial (preservative) function. (Exhibit 8 at A039-A041, Long Tr. at pp. 408-09; 445, lines 1-8)[2]; *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265, 278 (D. Md. 1998). Regarding the solvent function, Dr. Anderson testified that, as taught by the '249 patent,

(Exhibit 17 at A133-A134, Anderson Depo. pp. 72-73). Even in his deposition, Dr. Anderson admitted that ethanol in ranitidine formulations, both as taught in the '249 patent, and as used in Glaxo's syrup. (*Id.* at A134, p. 73)

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[2] Citing to the trial transcript of Dr. Long's testimony in *Glaxo v. Pharmadyne*.

Dr. Anderson, however, did no analysis to determine whether the in Teva's formulation performs the function of (*Id.* at A131, p. 64)

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He also did not analyze whether the in Teva's formulation acts as (*Id.* at A130, p. 58)

Dr. Anderson, therefore, provides no opinion concerning whether performs all of ethanol in the '249 patent. Dr. Anderson's report and deposition show that Glaxo has no proof that the in Teva's formulation provides all of the same functions, or their substantial equivalent, of the functions performed by ethanol in Glaxo's patent. Under *Graver Tank*, this is a fatal lack of proof under the function, way, result test.

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C. The Experts Have Opposite Conclusions On Whether In Teva's Formulation Stabilizes Ranitidine In Any Manner.

Dr. Kibbe also contradicts Dr. Anderson's analysis concerning whether stabilizes ranitidine in Teva's formulation as claimed by the '249 patent. Dr. Kibbe's rebuttal report explains in detail that

(Exhibit 16 at A113-A116, ¶¶ 45-52). Indeed, Dr. Kibbe's analysis of the same data Dr. Anderson reviewed supports the conclusion that

(*Id.* at A115-A116, ¶ 52.)[3]

Dr. Anderson also admitted in his deposition that

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(Exhibit 17 at A121-A123, Anderson Depo. pp. 20-22). For instance, with reference to Exhibit 6 of Dr. Anderson's first report,

(Exhibit 17 at A124-A126, Anderson Depo. pp. 25-27).

Moreover, Dr. Anderson (at least in his expert report) asserts that

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(Exhibit 18 at A151-152, ¶ 61; Exhibit 17 at A127-A129, Anderson Depo. pp. 31-33). In fact, when comparing two batches of solution with

to two

, in three of the possible four comparisons, the lower confidence level from the Teva formulation overlaps with the upper confidence level of the Glaxo formulations without ethanol. In three of the four tests, Teva's formulation did not improve ranitidine stability in a statistically significant manner.

[3] Glaxo's brief seems to suggest that the test for stability is whether the applicant to the FDA asks for a 24-month stability rating or not. (Glaxo Brf. at pp. 2, 5 and 16.). This is not the test used by Dr Hempenstall in the prosecution of the '249 patent, and it is not the test used by its own expert, Dr. Anderson.

D. Glaxo Has Not Analyzed Whether Alone Stabilizes Ranitidine in Teva's Generic Formulation.

There is no evidence before this Court that compares Teva's formulation with to Teva's formulation without . The only comparison presented by Glaxo (Dr. Anderson) is an analysis of Teva's formulation compared to "the prior art formulation," Glaxo's formulation without ethanol. Dr. Anderson admitted in his deposition that

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(Exhibit 17 at A135-136; Anderson Depo. pp. 197-198.) He did not make this comparison even though he testified that it would have been relatively routine for Glaxo or another independent lab[4] to have done so. (*Id.* at A137-A138, pp. 211-212). Aside from any direct proof of infringement, the lack of testing supports an inference that Dr. Anderson suspected that a head-to-head comparison of the Teva formulation with and without ethanol would have resulted in a showing of no stabilizing effect for That is why he did not do this highly probative and relatively simple test.

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There is ample evidence suggesting that other components of Teva's formulation act to stabilize the solution, and Glaxo has not even attempted to prove that has an additional stabilizing effect on Teva's formulation, much less the sole excipient responsible for a "substantial" enhancement, as taught by the '249 patent. The undisputed evidence shows that Teva's formulation is different in many respects from

[4] Although Glaxo repeatedly declares Dr. Anderson's analysis to be "independent," in fact it is not. Dr. Anderson extrapolated from the existing data to reach his conclusions. (Exhibit 17 at A119-A120, Anderson Depo. pp. 15-16). (*Id.* at A134D-E, Anderson Depo. pp. 142-143). His deposition may also have uncovered data that (*Id.* at A134A-E, Anderson Depo. pp. 139-143). His analysis is in no way independent, as Glaxo repeats throughout its brief.

Glaxo's Zantac® syrup. (Glaxo Brf. at p. 13, table 1) (providing a formulation comparison between Glaxo and Teva's formulations). The Teva formulation, of course, differs from Glaxo's syrup in that it has and not ethanol. (*Id.*)

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There are further important differences. Teva's formulation includes more . (*Id.*) Both ingredients are listed in Teva's ANDA application as " " (Exhibit 19 at A158, document T 00167). Teva's formulation also lists (Glaxo Brf. at p. 13, table 1). In Teva's formulation, there is than is present in Glaxo's syrup. (*Id.*) Except for the amount of ranitidine and the amount of the other buffering agent, no other ingredient in Teva's formulation contains the same amount as the corresponding ingredient in Glaxo's Zantac® syrup. (*Id.*)

There is no dispute that the presence of buffering agents and preservatives in a ranitidine formulation significantly improves the stability of ranitidine oral formulations. Dr. Anderson, in fact, states in his rebuttal report that

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(Exhibit 20 at A162-A163, Anderson Rebuttal Report, April 24, 2006 at ¶ 23). Dr. Anderson's opinion, however, flatly contradicts another Glaxo patent.

British Patent No. 2,142,820, the "Padfield" reference, states "the shelf life of aqueous based formulations containing ranitidine . . . may be significantly enhanced if the pH of the formulation is adjusted within the range of 6.5-7.5." (Exhibit 11 at A050, lines 19-21) (D.I. No. 105) (emphasis added). Padfield also teaches that the pH of the

formulation "is adjusted on manufacture within the range 6.5-7.5 by means of the use of suitable buffer salts . . .." (Exhibit 11 at A050, lines 31-32).[5] As in the Padfield reference, an early development report[6] associated with Teva's formulation states that

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(Glaxo Exhibit 27, attached to Langer Decl., D.I. Nos. 99 and 100).

It is the not the that stabilizes Teva's formulation. This is how it was designed. The Padfield patent, although owned by Glaxo, has now expired and is available for the public to use. Glaxo's own Padfield patent and Teva's (Novopharm's) development report both consistently conclude that

Teva's formulation also contains Glaxo's Zantac® syrup. (Glaxo Brf. at p. 13). Dr. Anderson contends that , but Dr. Kibbe disagrees. (Exhibit 16 at A116, Kibbe Rebuttal Report, April 24, 2006 ¶¶ 53-57). Dr. Kibbe concludes that

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(*Id.* at ¶ 55.)

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[5] U.S. Patent 4,585,790 to Padfield (Exhibit 21) is the corresponding U.S. patent to British Patent 2,142,820. The identical language cited above can be found at Exhibit 21 at A169, Col. 1, lines 27-31 and Col. 1, lines 48-50.

[6] As explained in the following section, the development report, authored by Novopharm (a Canadian company that Teva acquired six years ago) was produced by Teva in February of 2005.

[7] Although Dr. Anderson is of the opinion that the fact is that he never compared Teva's to the same product without (Exhibit 17 at A135-138, Anderson Depo. pp. 197-198; 211-212). Such a comparison could have eliminated the effect of , both solutions being equal, but he did not perform this test, although it would have been routine for either Glaxo or another lab to have done so.

Glaxo certainly knows how to analyze the stability of ranitidine formulations. In fact, Dr. Hempenstall declared during prosecution of the '249 patent that "[t]he advantageous effect resulting from the addition of ethanol to an aqueous based ranitidine formulation can readily be determined by comparing the stability of the ranitidine in a formulation according to the present invention and the same formulation but without the ethanol added." (G000209, Dr. Hempenstall Decl. at ¶ 5)[8] (emphasis added). Glaxo has not done this comparison with Teva's formulation and, therefore, cannot state what, if any "advantageous effect" results from the use of in Teva's formulation.

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Dr. Kibbe explains that

(Exhibit 15 at A097-A098, ¶¶ 84-86). Dr. Kibbe explains that

(Exhibit 16 at A107, Kibbe Rebuttal Report, April 24, 2006 ¶ 22). Dr. Kibbe also notes that

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conflict with Dr. Anderson's conclusion. (*Id.* at A104-105, ¶¶ 14-16.) Ultimately, Dr. Kibbe concludes that

(*Id.* at A108, ¶ 29.)

[8] File history documents, referenced herein within the range G000111 through G000308, are attached as Exhibits 2 and 3 to the Joint Claim Construction Statement filed on June 30, 2006 (D.I. Nos. 106-107).

Moreover, Teva has learned in discovery that another Glaxo scientist, Dr. Bird, held an opinion internally at Glaxo similar to Dr. Kibbe's in the present matter. Both are contrary to Dr. Anderson's supposed "independent analysis." Dr. Bird analyzed Glaxo's stability data and concluded that

(Exhibit 12 at A054) (D.I. No. 105) (emphasis added). She stated, however, that

(*Id.*)

(emphasis added). Yet, Dr. Hempenstall, when he submitted his Declaration to the Patent Office, omitted some of Glaxo's stability data and concluded that the ranitidine stability was "a highly significant and valuable improvement." (G000211).[9] Notwithstanding the inference that Dr. Hempenstall intended to deceive the Patent Office, there is certainly objective, factual, and independent evidence corroborating Dr. Kibbe's conclusions in this matter.

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F. The Experts Disagree On The "Proportionality" Of The Amounts Of Ethanol Recited In Claims 2-3 and 11-12.

Dr. Kibbe, in his rebuttal report, specifically takes issue with Dr. Anderson's conclusion that

(Exhibit 16 at A111, ¶ 39)

Dr. Kibbe also notes,

[9] Both Dr. Hempenstall and Dr. Anderson omitted data in their analysis and both concluded that ethanol Dr. Bird looked at (Exhibit 12 at A054) (D.I. No. 105).

This amount far exceeds the volume ranges recited in claim 2-3, and 11-12 of the '249 patent. (Exhibit 16 at A111-A112, Kibbe Rebuttal Report, April 24, 2006, ¶¶ 39-42).

G. The "Novopharm Development Report" Alleged To Have "Gone Missing" Is Attached As Exhibit 27 To The Langer Declaration Supporting Glaxo's Opening Brief.

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The quest for the so-called "Novopharm Development Report" is a tempest in a teapot, stirred by Glaxo alone. A careful review of the documents relied on by Glaxo shows that the substance of what several witnesses have identified as the "Novopharm Development Report" was located and produced to Glaxo on February 11, 2005, months before Glaxo first moved this Court for its production. (Exhibit 22 at A171). Indeed, Glaxo relies on this very document that it claims has "gone missing" in its moving papers to construct its tenuous inferences of copying by Novopharm. (Glaxo Exhibit 27 to Langer Decl., D.I. Nos. 99 and 100).

Unraveling Glaxo's deception concerning the "Novopharm Development Report" requires some context. Teva acquired Novopharm in April of 2000. (Exhibit 23 at A172-A173).[10] Teva adopted Novopharm's

(Exhibit 2 at A008) (D. I. No. 105). An email from a Novopharm employee dated September 9, 2004, was produced to Glaxo on February 11, 2005, document no. T 07268. (Glaxo Exhibit 30 to Langer Decl.). This email to Sarah Lahtinen, a Director of

[10] Teva Press Release, April 5, 2000, www.tevapharm.com/pr/2000/pr_237.asp. The acquisition occurred more than six years ago. Teva's acquisition is hardly "recent," as suggested by Glaxo. (Glaxo Brf. at p. 2) (describing Novopharm as "a recently acquired wholly-owned subsidiary of" Teva.).

Regulatory Affairs with Novopharm, asks another employee to

for the solution at issue to see if Novopharm's prior product development team had

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(*Id.*) (emphasis added).

The email was apparently printed out by Ms. Lahtinen, and she wrote the numbers of seven trials on the print-out of the email. (*Id.*) She then sent the print out to another person: (*Id.*) The very next page in the document production after the printed email with the written notes (*Id.*) is a copy of the (Glaxo Exhibit 27 to Langer Decl., p. T07269). Half way down the page is a section entitled (*Id.*) (emphasis added). the development process of Novopharm as it developed the formulation prior to Teva's acquisition of Novopharm. (*Id.* at pp. T07269-71.) The following pages include the same seven trials that Ms. Lahtinen listed on the print-out of the email. (*Id.*) The is the identified in the September 9, 2004, email.

During the May 19, 2005, deposition of Tamas Szederkenyi, Novopharm's Senior Director of Analytical Research & Development, Glaxo questioned Mr. Szederkenyi extensively about this series of documents, all marked as a single document, deposition Exhibit No. 7. (Exhibit 24 at A175-A183, Szederkenyi Depo. pp. 157-165; Exhibit 25 at A184-A205, Depo. Exhibit 7). When Glaxo took the deposition of Teva's corporate designee on the subject of Teva's efforts to locate documents responsive to Glaxo's discovery requests including the "Development Report,"[11] however, Glaxo separated the

[11] The excerpts from this deposition, reproduced at pp. 29-30 of Glaxo's Brief, are taken out of context. The record reflects that the same witness was questioned extensively about the efforts

September 9, 2004, email from the documents immediately following it. (Compare Glaxo Exhibit 30 (first page) and Glaxo Exhibit 27 (and following pages) with Exhibit 25, Depo Exhibit 7). Glaxo questioned the Teva designee using the email and the ' section as if both were separate documents, leaving the false impression that the report referenced in the email and the email had not been produced together and did not belong together. (Exhibit 26 at A219-221, Wrigley Depo. pp. 87-89).

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Glaxo exacerbated the confusion it engendered regarding the development report by stubbornly querying Novopharm witnesses that lacked any foundation to comment about a "Novopharm Development Report." Mr. Fernandes, for instance, was shown the September 9, 2004, email and asked (Exhibit 27 at A223, Fernandes Depo. p. 141).[12] He responded:

(*Id.*)

Undeterred, Glaxo continued, stating

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that Teva in fact goes through to search for and locate documents when requested in litigation. (Exhibit 26 at A207-A215, Wrigley Depo. pp. 56-64). The designee was asked whether such a search was conducted in this case for " and the witness responded (*Id.* at 69.) She was also asked whether a search was done for and she responded, after an agreement was reached concerning the privilege, she responded (*Id.* at A217, p. 70.) The designee also testified that she searched and she responded (*Id.*) She was also asked and she responded (*Id.* at A218, p. 72.) The designee is a member of Teva's in-house legal department, so (understandably) questions that might reflect communications with outside counsel were cautiously guarded throughout the deposition. However, when put into the appropriate context, Glaxo was clearly not "totally shutdown" in its inquiry concerning what Teva has done to look for and produce documents in this case. This is most likely why Glaxo has not, before serving its summary judgment motion, sought to overrule any objection or instruction occurring in the deposition of Ms. Wrigley.

[12] Glaxo highlights Mr. Fernandes' testimony to prove that the development report existed and what was in it. (Glaxo Brf. at pp. 27-28). In fact, Mr. Fernandes' testimony was all speculation and the deposition testimony explicitly confirms this. (Exhibit 27 at A223-A224, Fernandes Depo. pp. 141-142).

(*Id.* at A223-224, pp.141-142.) Mr. Fernandes then offered

(*Id.* at A224, p. 142.) A few pages later in the deposition, Glaxo turned its query to the tables on the documents following the email, where Mr. Fernandes testified

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(*Id.* at A225-226, pp. 145-146.) Glaxo did not show the two documents together to Mr. Fernandes, in their proper context, to even help educate Mr. Fernandes' speculation.

Regardless, by divorcing the September 9, 2004, email from its context in the production, and inquiring of Teva's corporate designee about a document created by Novopharm in the mid-1990s, Glaxo created the confusion. Glaxo, in fact, has had the document it alleges has "gone missing" since February of 2005.

IV. ARGUMENT

Teva maintains that Glaxo is not entitled to expand the scope of its claims to include anything but ethanol under the doctrine of equivalents. Absent reliance on the doctrine of equivalents to expand the scope of its patent claims beyond the use of ethanol to stabilize ranitidine, Glaxo's infringement claims fail as a matter of law, as the term "ethanol" is common to all claims of the '249 patent. The legal and factual basis supporting summary judgment of non-infringement is set forth in detail in Teva's Brief In Support Of Motion For Summary Judgment Of Non-Infringement, and is incorporated herein. (D.I. No. 104). For the reasons stated in that brief, Glaxo's motion should be denied.

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Should this Court deem Glaxo entitled to some expansion of its patent under the doctrine of equivalents, then Glaxo has failed to prove that the in Teva's formulation is the equivalent of the "ethanol" in the claims of the '249 patent. At the very least, there are fact issues in dispute about the alleged equivalency of

A. Teva, Not Glaxo, Is Entitled To Summary Judgment.

Rule 56(c) permits summary judgment where there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). In considering whether a triable issue of material fact precludes Glaxo's motion, the Court "must review the evidence and construe all inferences in the light most favorable to the non-moving party." *Petrocelli v. DaimlerChrysler Corp.*, 2006 U.S. Dist. LEXIS 11972, * 10-11 (D. Del. 2006) (attached as Exhibit 32 at A244-A249) (*citing Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir. 1976)). Further, this Court has recognized that, when conducting such a review, it "should not make credibility determinations or weigh evidence." *Id.* at * 11 (*citing Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000)). Here, Teva is entitled to summary judgment of non-infringement, as Glaxo has failed to establish even a *prima facie* case of infringement under the doctrine of equivalents. *See Microsoft Corp. v. IQ Tech., Inc.*, 1993 U.S. App. LEXIS 16128, * 8 (Fed. Cir. 1993) (attached as Exhibit 33 at A250-A252) (Patentee has the burden to prove infringement even in declaratory judgment for non-infringement actions). If this Court believes that Glaxo has presented a *prime facie* case of equivalents, then there are fact issues that preclude summary judgment.

1. Glaxo Lacks Sufficient Evidence Showing Teva's Formulation Meets The "Ethanol" Claim Limitation Under The Doctrine Of Equivalents.

a. *The Law Of The Doctrine Of Equivalents*

Analyzing patent infringement is a two-step process. First, standing in the shoes of one skilled in the art, a court should construe any disputed claim terms. *Playtex Prods., Inc. v. Proctor & Gamble Co.*, 400 F.3d 901, 905-06 (Fed. Cir. 2005). Second, a court should compare the properly construed claims to the accused product or process. *Id.* at 906.

The doctrine of equivalents, when applied too broadly, "conflicts with the definitional and public-notice functions of the statutory claiming requirement." *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29 (1997). As a result, the Supreme Court has been clear that "the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." *Id.* Furthermore, even as applied to individual elements, the doctrine "is not allowed such broad play as to effectively eliminate that element in its entirety." *Id.* "A focus on individual elements and a special vigilance against allowing the concept of equivalence to eliminate completely any such elements" is critical to the analysis of whether a claim element is met under the doctrine of equivalents. *Id.* at 40.

For this reason, application of the "triple identity" test, albeit imperfect, is appropriate here. This test, one that Glaxo concedes is "the most common expression" of the test of equivalents, states that equivalent infringement lies where "a substitute element matches the function, way, and result of the claimed element." *Id.* at 40. Glaxo relies solely on the doctrine of equivalents to establish its infringement claim against

Teva, as its claims are literally limited to "ethanol." As articulated by *Graver Tank*, the alleged equivalent must perform substantially the same function in substantially the same way to achieve substantially the same result. *Graver Tank*, 339 U.S. at 608.

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b. *"Ethanol" Means "Ethanol" And Nothing More.*

Glaxo disclosed and claimed its invention narrowly, claiming ethanol as the stabilizing agent. It claimed narrowly even though the inventor, Dr. Long, foresaw that also would stabilize ranitidine. He abandoned because it did not perform the other necessary functions in the ranitidine solution, such as the antimicrobial function. Teva's brief supporting its motion for summary judgment completely argues this and this argument will not be repeated here. Glaxo is not entitled to a finding that is the equivalent of ethanol as a matter of law. (*See* D.I. No. 104 at pp. 20-36).

c. *Glaxo Has Failed To Prove That Has Of Ethanol In A Ranitidine Solution.*

Under either parties' proposed construction of the term "ethanol," Glaxo's evidence of infringement under the doctrine of equivalents is insufficient as a matter of law, because Glaxo has no evidence that the in Teva's formulation performs each that ethanol performs. In this case, Glaxo must show that performs that its expert admits ethanol performs:

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(Exhibit 1 at A002, Anderson Report, March 16, 2006, ¶ 40).

Glaxo, however, presents no evidence that performs

and (at best) there is a fact issue underlying whether performs

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During his deposition, Dr. Anderson admitted that he had no evidence that

(Exhibit 17 at A131, Anderson Depo. p. 64)

Dr. Anderson also admitted that

(Exhibit 17 at A130, Anderson Depo. at p. 58)

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Moreover, Dr. Long , the inventor of the '249 patent, abandoned the use of because it did not provide an antimicrobial function. (Exhibit 8 at A039-041, Long Tr. at 408-09; 445, lines 1-8). Using the evidence from Glaxo's own expert and inventor, Glaxo has failed to prove that performs of ethanol in the invention. This, alone, justifies summary judgment in favor of Teva on Glaxo's infringement claim.

With respect to (as a stabilizer for ranitidine), Glaxo also cannot meet its burden of proof. Glaxo has never analyzed whether the in Teva's formulation is the cause of that formulation's measured shelf life. At best, Glaxo's evidence shows that Teva's formulation, when compared to Glaxo's formulation without ethanol has a longer shelf life. There is no evidence, however, comparing the

shelf life of Teva's formulation with to the same formulation without Consequently, there is no way to know, based on the evidence before the Court, whether has anything whatsoever to do with the stability of Teva's formulation. In fact, the clear evidence suggests that Teva's use of

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maintains the stability of ranitidine in Teva's formulation. (Glaxo Exhibit 27, p. T072700) (Novopharm development report, noting

Glaxo has the burden to prove infringement by a preponderance of the evidence. Glaxo has failed to meet its burden here.

2. Glaxo Also Has Failed To Prove That Teva's Formulation Meets the "Stabilizing Effective Amount of" Element of Claims 1-10.

The parties have differing positions on the appropriate construction of "stabilizing effective amount of," as recited in Claim 1 and incorporated into Claims 2-9 by dependency. Under either party's construction, however, Glaxo has failed to meet its burden of proof on this element. As explained above, there is no evidence before this Court analyzing whether the addition of is the cause of the stability of Teva's formulation. Glaxo has only compared Teva's formulation to Glaxo's formulation without ethanol. This proves nothing with respect to the effect (if any) of on the stability of ranitidine in Teva's formulation. Indeed, this head-to-head comparison is what Glaxo argued to get its patent. (G000209, ¶ 5). Summary judgment in Teva's favor on Glaxo's claim of infringement is therefore additionally proper on this basis.

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B. Alternatively, Genuine Issues Of Material Fact Preclude A Finding That Any Claim Element Is Satisfied Under The Doctrine Of Equivalents.

Assuming the Court finds that Glaxo has presented sufficient evidence to survive Teva's Motion for summary judgment, then Glaxo's motion should be denied because material facts are in dispute that hinge upon the veracity and credibility of Glaxo's expert, and the motivation behind the development of Teva's formulation. *Legett & Platt, Inc. v. Hickory Springs Mfg. Co.*, 285 F.3d 1353, 1359-60 (Fed. Cir. 2002) (reversing summary judgment of non-infringement where expert witness and fact witness testimony created issues of fact). This Court has recognized, as have other courts, that summary judgment is particularly inappropriate where the declaration of the non-moving party's expert witness demonstrates issues of fact exist. *Cryovac Inc. v. Pechiney Plastic Packaging, Inc.*, 430 F. Supp. 2d 346, 356 (D. Del. 2006) (finding disagreement among experts as to whether prior art would motivate one of ordinary skill in the art to make invention at issue "creates a genuine issue of material fact, and thus, summary judgment on obviousness must be denied."); *see also Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1144 (9th Cir. 1997) ("Summary judgment is inappropriate where an expert's testimony supports the nonmoving party's case.").

1. The Competing Expert Opinions of Glaxo and Teva Preclude Summary Judgment Against Teva.

It is improper for a court to attempt to weigh the credibility of an expert's opinion on a motion for summary judgment. *State Farm Fire & Casualty Co. v. Estate of Jenner*, 856 F.2d 1359, 1365 (9th Cir. 1988). Patent cases are no different; a genuine issue of material fact exists where the parties' expert witnesses give conflicting opinions as to the structure and operation of the patents and products in question. *Hilgraeve Corp. v.*

McAfee Assocs., Inc., 224 F.3d 1349, 1353 (Fed. Cir. 2000) (vacating grant of summary judgment because the parties' experts disagreed on how the patented software interacted with the computer operating system). Assuming Glaxo is legally permitted to invoke the doctrine of equivalents, and further assuming Glaxo has set forth sufficient evidence to make out a *prima facie* case of infringement, Glaxo's motion should still be denied on the sole basis that both parties' experts draw opposite conclusions on three material issues.

First, both Dr. Anderson and Dr. Kibbe disagree on the ultimate question of whether can be considered an equivalent of ethanol in any chemical formulation, an issue that effects a finding of infringement of every claim of the '249 patent. Dr. Kibbe explained, in his first expert report, that

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(Exhibit 15 at A095-A097, ¶¶ 76-83.) Dr. Kibbe explained that (*Id.*) Further, Dr. Kibbe explained that

(*Id.*)

and ethanol have distinctly different physical and chemical characteristics. (*Id.*, ¶¶ 80-81.) Dr. Kibbe explains that

(*Id.* at A097-098, ¶¶ 84-86.)

Dr. Kibbe explains that

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(Exhibit 16 at A107, ¶ 22.) Dr. Kibbe also notes that

a finding in conflict with Dr. Anderson's conclusion. (*Id.* at A104-A105, ¶ 15). Ultimately, Dr. Kibbe

concludes that Redacted

(*Id.* at A108, ¶ 29).

Second, both experts draw different conclusions from the data used by Dr. Anderson to infer that stabilizes ranitidine in any amount. (*Supra*, "Facts" § C). This issue effects any finding of infringement of Claims 1-10 of the '249 patent, all of which contain the "stabilizing effective amount of" limitation. Dr. Kibbe's central position is that Dr. Anderson's

(Exhibit 16 at A113-A116, ¶¶ 45-52). This is so because Dr. Anderson failed to account for or analyze whether ethanol and might effect the stability of ranitidine. (*Id.* at A116, ¶ 54). Dr. Anderson, of course, does not agree.

Third, the experts have opposing views on whether the specific numerical ranges of ethanol, as recited in claims 2-3 and 10-11, are mathematically proportionate to the amount of in Teva's formulation. (*Supra*, "Facts" § F). Indeed, the generic formulation at issue in *Pharmadyne* was different from Teva's proposed formulation, principally in that Teva's formulation uses Redacted while the generic at issue in *Pharmadyne* used 12.5% (w/v) *Pharmadyne,* 32 F.Supp. 2d at p. 281. Interestingly, Glaxo's retained expert in *Pharmadyne* concluded that 12.5% (w/v) was equivalent to 7.5% (w/v) ethanol. *Id.* at 287. In this case, Glaxo's expert concludes that Teva's is equivalent to 7.5% (w/v) ethanol. The two Glaxo experts even disagree.

Employing Dr. Anderson's ratio methodology, and assuming (as the *Pharmadyne* court held) that 12.5% is equivalent to 7.5% ethanol, the ratio is 1.67 (12.5% ÷ 7.5%). For the 7%-8% EtOH claim (claim 2), the proportionate upper limit of would be 13.33% (1.67 multiplied by 8). (as used in Teva's formulation) is outside this range, and would therefore be outside of the scope of the percentage limitation of claim 2 of the '249 patent.

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Each of these issues, alone or in combination, (assuming Glaxo has presented a *prima facie* case at all) precludes summary judgment of infringement in this case. *See, e.g.*, *Hilgraeve Corp.*, 224 F.3d at 1353.

2. Whether Teva's Formulation Is Substantially Different From The Claimed Invention Is A Question Of Fact.

The facts before this Court support the conclusion that Novopharm's development of the ranitidine formulation that ultimately became Teva's formulation was a carefully constructed effort to design around the claims of the '249 patent, while at the same time developing a solution that was bioequivalent to Glaxo's Zantac® syrup. As stated by the Supreme Court in *Graver Tank*, "[a] finding of equivalence is a determination of fact," predicated on the "balancing of credibility, persuasiveness and weight of evidence." 339 U.S. at 609-610.

Subrata Mazumder, Teva's corporate designee on the subject of Teva's development of its formulation, testified that he was instructed to develop a formulation that did not contain ethanol because of (Exhibit 29 at A233, Mazumder Depo. p. 82). Novopharm's development report confirms that one of the specific challenges facing Mr. Mazumder

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(Glaxo Exhibit 27, p. T 07270). The same report lists as in the formulation, and explicitly states that (*Id.*) There is no mention in the report that the purpose of in the formulation is to stabilize ranitidine. Moreover, excluding water, only 2 of the 12 other ingredients in Teva's formulation are in the same amounts as the corresponding ingredients in Glaxo's Zantac® syrup. (Glaxo Brf. at p. 13). Of course, is not in the Zantac® syrup at all. (*Id.*)

A reasonable fact finder could conclude, based on this evidence, that the development of the accused formulation was the action of "an incremental innovator designing around the claims, yet seeking to capture as much as is permissible of the patented [formulation]." *Warner-Jenkinson*, 520 U.S. at 36. Such conduct is not only perfectly appropriate, but is the type of conduct that the patent system encourages. The purpose of a patent claim, after all, is to provide notice to competitors regarding the scope of the patent grant. *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 232 (1942) ("The inventor must inform the public . . . of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not") (internal quotes omitted). A full and complete disclosure of the invention allows competitors to understand the bounds of the invention and encourages innovation by challenging those competitors to explore and create non-infringing uses of the claimed invention. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). The Supreme Court has repeatedly emphasized that the "carefully

crafted bargain" at the heart of the United States patent system "depends almost entirely upon a backdrop of free competition in the exploitation of unpatented designs and innovations." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989).

While Glaxo, based on nothing but inference, characterizes the development of Teva's formulation as the "actions of a copyist," the evidence compels the opposite conclusion. Regardless, when considering the evidence on a motion for summary judgment, all inferences of fact must be construed "in the light most favorable" to Teva, the non-moving party on this issue. *Petrocelli*, 2006 U.S. Dist. LEXIS 11972 at * 10-11 (Exhibit 32). There is sufficient evidence in the record to enable a reasonable trier of fact to find that Novopharm's development of Teva's ANDA formulation were efforts to design around the '249 patent claims, a fact that does not support a finding of infringement under the doctrine of equivalents. Glaxo's motion must, therefore, be denied.

3. Glaxo Misstates The Law Concerning The Test For Infringement Under The Doctrine Of Equivalents.

As stated above, the development of Teva's formulation was a concerted effort to design around the '249 patent, not "the actions of a copyist," as Glaxo contends. Glaxo's attempt (at p. 15 of its brief) to elevate evidence pertaining to alleged "copying" beyond its proper context should be weighed with great skepticism by this Court, if not rejected out of hand. Glaxo's sole basis for the assertion that such evidence allows a fact finder to infer that the alleged infringer has made only an insubstantial change is the Federal Circuit's 1995 opinion, *Hilton-Davis Chemical Co. v. Warner-Jenkinson Co. Inc.*, 62 F.3d 1512 (Fed Cir. 1995). This is the very opinion that was reversed by the Supreme

Court in its 1997 *Warner-Jenkinson* decision. *Warner-Jenkinson*, 520 U.S. at 41. (ruling that because the Federal Circuit "did not consider all of the requirements as described by us today, particularly as related to prosecution history estoppel, and the preservation of some meaning for each element in a claim, we reverse and remand for further proceedings consistent with this opinion." (emphasis added)).

The Supreme Court's reversing opinion specifically rejected the Federal Circuit's suggestion that an alleged infringer's behavior (whether seen as copying or as efforts to design around a patent) permits a rebuttal inference concerning whether the accused equivalent represents a substantial change. 520 U.S. at 36. The Supreme Court was explicit in rejecting the very proposition of law that Glaxo proposes:

> According to the Federal Circuit, a person aiming to copy or aiming to avoid a patent is imagined to be at least marginally skilled at copying or avoidance, and thus intentional copying raises an inference--rebuttable by proof of independent development--of having only insubstantial differences, and intentionally designing around a patent claim raises an inference of substantial differences. This explanation leaves much to be desired. At a minimum, one wonders how ever to distinguish between the intentional copyist making minor changes to lower the risk of legal action, and the incremental innovator designing around the claims, yet seeking to capture as much as is permissible of the patented advance.

520 U.S. at 36-37 (emphasis added). Glaxo, by parenthetically citing the underlying Federal Circuit decision, implies that it would be appropriate for a fact finder to infer that copying by the alleged infringer means the alleged equivalent is not substantially different from the patent at issue. This is not the law. The Supreme Court ruled that "intent plays no role in the application of the doctrine of equivalents," and relegated evidence pertaining to the independent development of the alleged infringer as simply "probative" evidence of whether one of ordinary skill in the art would consider the

alleged equivalent to be interchangeable with the element of the patent claim at issue. 520 U.S. at 36.

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4. **Does Not Support Any Inference Of Infringement By Teva.**

The same principal applies to the inferences that Glaxo attempts to draw from the fact that

Despite admitting that "Novopharm did not expressly acknowledge that the *Pharmadyne* decision was the reason for" Novopharm's decision, Glaxo nonetheless asks this Court to infer that the *Pharmadyne* decision was the reason for Novopharm's withdrawal. (Glaxo Brf. at pp. 26-27). Such an inference is not permitted on summary judgment. *Petrocelli*, 2006 U.S. Dist. LEXIS 11972 at * 10-11 (Exhibit 32). Glaxo asks this Court to further infer (assuming Novopharm's decision was related to the *Pharmadyne* decision) that Novopharm's decision is somehow relevant to Teva's actions when it adopted and developed its own ANDA formulation, many years later. Glaxo's conclusions are nothing but speculation, much less a reasonable inference of fact.

and not the negative inference that Glaxo urges in its favor.

C. The *Glaxo v. Pharmadyne* Decision Is Not Binding Or Persuasive Precedent.

Glaxo's recitation of the facts and conclusions of the court in *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265 (D. Md. 1998) has no relevance whatsoever to the issues before this Court. The accused formulation in *Pharmadyne* also

contained 12.5% and 25% sorbitol in comparison to Teva's formulation with *Pharmadyne*, 32 F. Supp. 2d at 281. The *Pharmadyne* formulation also included anhydrous citric acid, saccharin sodium, and methyparaben,[13] *Id.* at 278. The *Pharmadyne* decision has no bearing on Teva's formulation, and Teva has a constitutional right to its own independent adjudication of whether its formulation infringes the '249 patent in any manner.

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Moreover, in *Pharmadyne*, Glaxo's U.S. Patent No. 4,585,790 (Padfield) also was at issue. *Pharmadyne*, 32 F. Supp. 2d at 268. The '790 patent is the U.S. equivalent of the '820 "Padfield reference" that Glaxo faced during prosecution of the '249 patent. (Exhibits 11 and 21). The Padfield reference addressed the use of "suitable buffer salts" to adjust the pH level of ranitidine formulations. (Exhibit 21 at A169, Col. 1, l. 50). Glaxo stated, in the '790 patent, that "[w]e have surprisingly found that the shelf life of aqueous based formulations containing ranitidine . . . may be significantly enhanced if the pH of the formulation is adjusted within the range of 6.5-7.5." (*Id.*, Col. 1, ll. 27-31). The defendant in *Pharmadyne*, was held to have infringed the '790 patent. 32 F. Supp. 2d at 271.

(Glaxo Exhibit 41, p. LVM 0045).

The developers of Teva's formulation were free to use, and in fact did use,

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because the '790 patent has now expired. (Glaxo Exhibit 27, p. T07270). The Teva formulation was developed in an entirely different context than the *Pharmadyne* formulation and contains entirely different components.

[13] Methylparaben was eliminated from Glaxo's NDA formulation (Exhibit 18 at A144, ¶ 38).

For this reason, and for the reasons stated in Teva's Brief In Support Of Motion For Summary Judgment Of Non-Infringement, the *Pharmadyne* decision has no bearing under the facts before this Court.

D. There Is No Factual Or Legal Basis For The Extreme Evidentiary Sanction Glaxo Seeks.

Having failed to meet its burden of proof on the single issue of infringement before this Court, Glaxo resorts to misrepresenting the record to manufacture an untimely and false allegation of discovery misconduct so that it can be relieved of its burden of proof on the issue of infringement. As the authority relied upon by Glaxo makes clear, however, the evidentiary sanction that Glaxo seeks is the type of extreme sanction reserved only for extraordinary circumstances where a party deliberately and intentionally refused to comply with an explicit and direct order to produce discovery. *Spear v. Commissioner (Estate of Spear)*, 41 F.3d 103, 109 (3d Cir. 1994) (*citing Ins. Corp. of Ir. v. Compagnie Des Bauxites De Guinee*, 456 U.S. 694 (U.S. 1982)); *Liafail, Inc. v. Learning 2000, Inc.*, 2002 U.S. Dist. LEXIS 24803, *9-13 (D. Del 2002) (refusing to sanction Liafail immediately and first ordering Liafail to "correct its apparent wrongs") (Exhibit 28). Moreover, prejudice to the party complaining of the alleged loss of evidence is a critical factor to issuing such a punitive sanction. *Curtis T. Bedwell & Sons, Inc. v. International Fidelity Ins. Co.*, 843 F.2d 683, 691 (3d Cir. 1988) (listing prejudice as a factor in determining appropriate sanction for discovery misconduct).

Here, no discovery misconduct has occurred, no order was ever issued, and the very report that Glaxo claims has "gone missing" was in fact in Glaxo's possession all the time. Glaxo cannot possibly be prejudiced in any way. There is no basis for the relief Glaxo seeks.

Beyond the confusion Teva now has resolved for this Court concerning the document, confusion created by Glaxo, Glaxo should be ashamed of its misrepresentations to this Court concerning whether this Court ordered the production the document. Glaxo boldly proclaims that "[t]he Court ordered the Report produced in response to Glaxo's letter requests for assistance," followed by a cite to two hearings before the Court, one occurring on June 30, 2005, the other on October 7, 2005. (Glaxo Brf. at p. 28.) There was no such order from the Court in either hearing.

During the June 30, 2005, hearing, Teva explained that the development work at issue was "done for a division that was sold off and is now a separate company." (Exhibit 30 at A235, p. 10, ll. 19-20.) The Court inquired as to whether either party had engaged in an effort to acquire the documents from that company, and Teva advised that the efforts had just begun. (*Id.* at p. 10-11.) The Court admonished both parties to work together in the discovery effort, but ultimately stated that "there is really nothing for me to rule on right now and I'm not going to rule on it." (*Id.* at p. 11.) Contrary to Glaxo's representation, this Court did not order "the Report produced in response to Glaxo's letter requests for assistance." (Glaxo Brf. at p. 28.) This is a far cry from an "order" of this Court to produce the Report at issue, as Glaxo represents in its brief.

During the October 2005 hearing before this Court, Teva explained that it had done all that it could do to locate and produce development documents within its possession and control. (Exhibit 31 at A237-239, October 7, 2005 Hearing Transcript at pp. 11-13). Teva advised that some further documents may be in the possession and control of Pharmascience, a company that acquired a division of Novopharm not acquired by Teva. (*Id.* at A239-240, pp. 13-14.) Teva also attempted to convince Pharmascience

to voluntarily produce what documents it had, yet Pharmascience declined. (*Id.*) Teva advised Glaxo of this fact, and further updated the Court during the October 7, 2005, hearing, ultimately telling the Court that "We have nothing else to give." (*Id.* at A 241, p. 15).

This Court advised Glaxo that Teva's explanation as to its lack of control over Pharmascience, "sounds like a pretty good excuse to me." (*Id.* at A242, p. 23) (commenting further that "Pharmascience isn't owned, operated or controlled by Teva. If [Pharmascience] want[s] to stand on their rights under Canadian Law, I'm not sure what it is you want me to do in that regard, Mr. Murphy"). In response, Glaxo's counsel stated:

> MR. MURPHY: . . . Let me address Pharmascience. Given counsel's representations, I agree with you, there is nothing more we can ask of Teva and we won't. We'll pursue it if the client chooses to expend the resources to make a constitutional challenge to a Canadian statute, which I think is highly unlikely.

(*Id.* at A 243, p. 24.) As counsel predicted, Glaxo did not proceed with a "constitutional challenge" to the law in Canada, and (apparently) gave up the effort. The Court did not order the report produced at any time in this case.

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V. CONCLUSION

Glaxo should not be permitted to employ the doctrine of equivalents to expand its claims to include as a matter of law. Even if it is so permitted, summary judgment in favor of Teva on Glaxo's infringement claims is warranted. Glaxo has utterly failed to prove that any claim of the '249 patent is infringed by Teva's formulation because it has not analyzed whether performs all the functions of ethanol. Moreover, Glaxo has never compared Teva's formulation with the

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same formulation without , and cannot, therefore prove its infringement case. Assuming further that the Court rules that Glaxo has presented a *prima facie* case on its claims, those claims cannot be resolved on summary judgment because genuine issues of material fact mandate that Teva be given its opportunity to disprove Glaxo's claims at trial. Finally, Glaxo's request for a negative inference of patent infringement should be denied.

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Dated: July 28, 2006

CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on July 28, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on June 30, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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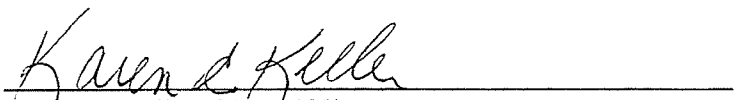

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